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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,642	10/01/1999	GILBERT BLAISE	ML/12482.11	6239

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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/402,642

Applicant(s)

BLAISE ET AL.

Examiner

Joseph F Weiss Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 9-11 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bathe (US 5558083) in view of Sato et al (US 4681099).

In regards to claims 1 & 9, Bathe discloses an injection system comprising a control unit (56), a valve assembly (valves 14, 20 & 24) which includes a valve and valve actuating means which allows for variable opening of the valve (24 & 24/72 interface), said valve actuating means being coupled to said control unit, a flow meter (46) for measuring inspiratory gas flow and being coupled to said control unit (60) to provide inspiratory gas flow data; wherein the control unit controls the valve assembly so that the variable opening of the valve is responsive to inspiratory gas flow in a conduit of a ventilator to achieve a predetermined concentration of the gaseous substance and the concentration may vary from injection to injection, and is fully capable of utilizing inspiratory data gathered over several inspirational phases, but does not explicitly disclose such. However, Sato disclose such (Col. 12 line 35 to col. 13 line 6). The references are analogous since they are from the same, field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Sato and used them with the device of Bath. The suggestion/motivation for doing so

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would have been to optimize the delivery of gases. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 2 & 10, the variable opening of the valve is proportionally responsive to the inspiratory gas flow in the conduit.

In regards to claims 3 & 11, the control unit opens the valve in response to the inspiratory gas flow when the flow exceeds a threshold indicative of an inspiratory effort and thus insures that gas is delivered only when the patient is in an inspiratory phase.

In regards to claim 16, Bathe discloses NO gas for use in the apparatus.

2. Claims 4-7 & 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bathe & Sato in view of Dietz (5074299).

In regards to claims 4 & 5 Bathe substantially discloses the instant application's claimed invention, but does not explicitly disclose an alarm that is actuated by detection of time in between inspirations in excess of predetermined thresholds or when a single inspiration phase exceeds a predetermined threshold. However, Dietz disclose such (col. 10, line 57- col. 11 line 15). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Dietz and used them with the device of Bathe. The suggestion/motivation for doing so would have been to insure the user received the

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proper dosage of gasses. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 6 & 14, the suggested device discloses a control unit, which can deactivate the injector based upon values received from monitoring user/device conditions, which would be indicative of an improper or "alarm".

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 7 & 15, Bathe discloses the use of a user input device (58) configured to receive inputs from a user and it is old and well known that such devices can incorporate data displays to a user.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

The amendment resolves the 35 USC 101 & 112 issues.


### ***Conclusion***

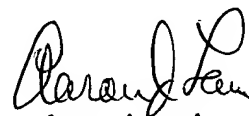
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jfweiss  
2/2/04

  
Aaron J. Lewis  
Primary Examiner